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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,628	11/08/2001	Fergal Conan Hill	674508-2008	9992

20999 7590 12/02/2003

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/007,628	HILL ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 36 is/are pending in the application.
- 4a) Of the above claim(s) 5, 7, 9, 22, 28, 35 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 4, 6, 8, 10- 21, 23-27, and 29- 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group II from response paper filed 3 November 2003 is acknowledged. Applicant's election of Group II is responsive to the requirement. Applicant also elects a species; however, no election of species is required. The traversal is on the ground(s) that Gro ES and T4 Gp31 are both cpn10 homologues, Group III is a subset of Group II, and that a search for Groups IV, V, and VI most likely will have coextensive search requirements as Groups I, II, and III, and the additional searches will be of no burden to the examiner. This is not found persuasive because the proteins, methods, and nucleic acids are distinct inventions as outlined in the Restriction Requirement. The elected invention is Group II and not Groups IV, V, or VI and the search is not mutually inclusive of each other because the search for Groups IV, V, and VI is not limited to the subject matter of Group II.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded of the following:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1- 4, 6, 8, 10- 21, 23-27, and 29- 33 are under consideration in this action. Claims 1, 3, and 4 are linking claims and claim 2 is generic and examined only as it reads on the elected invention. Because art was found on the linking claims, the search is limited to the elected invention.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

A signed and initialed copy of the IDS filed 8 November 2001 is enclosed.

Specification

This application is listed as a CIP and the transmittal letter indicates that the specification contains 56 sheets. The pages appear to be copies of PCT/GB00/01815. Applicant is requested to indicate what changes make this a CIP.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 4, 6, 8, 10- 21, 23-27, and 29- 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1- 4, 6, 8, as well as 10- 21, 23- 27, and 29- 34, it is not clear what the metes and bounds of the subunit or peptide structure are that have the recited function. It is also confusing because claims 1, 4, 6, and 8 refer to subunit

and it is not clear if this means part of multimer or if it is a portion or fragment of the polypeptide monomer. Claims 6, 8, and 10 are not clear as to the location of the insertion because there is no basis for numbering positions.

Claim 24 recites the limitation "oligomer" in line 1. There is insufficient antecedent basis for this limitation in claim 1. Claim 1 only recites polypeptide monomer. Claims 25- 27 recite "polypeptide", it is not clear if this refers to the monomer or oligomer of claim 24.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 11- 14, 16, 21, 23, 29, and 31- 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Terskikh (from IDS).

Terskikh discloses a polypeptide monomer that is capable of oligomerization comprising a heterologous sequence inserted into a subunit of an oligomerizable protein scaffold (abstract), that a heterologous amino acid is displayed at the C or N terminus (illustration on page 11), that oligomers may be homo- or hetero-oligomers or the oligomers are crosslinked (page 6), that can be used as a vaccine (page 8, top), that contains a ligand for a receptor for the heterologous sequence (page 9, top), that the heterologous peptide is at least

Art Unit: 1648

partly random (page 9, second paragraph), and that the polypeptide has biological activity (Example 4).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1- 4, 6, 8, and 10- 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 4, 6, 8, and 10- 18 of copending Application No. 10/007314.

Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following: both claim 1s are drawn to a polypeptide monomer capable of oligomerization, both claim 2s include T4 gp31 and E coli Gro ES and homologues, further dependent claims recite common structural features such as insertions, C and N terminals of the protein are formed by the polypeptide, the oligomer is a homooligomer, the oligomer is a heterooligomer, where the oligomer is a ring, and where the oligomer is a seven

Art Unit: 1648

membered ring. The claims differ in the exact locations marked for inserts. The ranges in the instant application are inserts between 15 and 34 and 54 and 67 and in the copending application there are recited as between 19 and 29 and 56 and 57. All positions included in the copending application are included in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is also noted that copending application 10/013314 "FUSION PROTEINS COMPRISING A FRAGMENT OF A CHAPERON POLYPEPTIDE" could also subject to Double Patenting. This application is not available because it is in pre-exam and it is not an IFW application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1648

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
November 26, 2003

James C. House
12/1/03
JAMES HOUSEL
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